**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF NEW YORK**

**MIQUEL CARIAS, JANET RAMIREZ, MICHAEL PICONE, EVELYN FLECHA, ZENA MATOS, on behalf of KAILEI MATOS, a minor, JAMIE NINO, and HALONA JAFFE, individually and on behalf of all others similarly situated,**

**Plaintiffs,**

**v.**

**MONSANTO COMPANY, a Delaware corporation; DOES 1-10, inclusive,**

**Defendants.**

**ELECTRONICALLY FILED**

**CASE NO. 2:15-CV-03677-JMA-GRB**

**REPLY MEMORANDUM IN SUPPORT OF MOTION TO DISMISS**

**ORAL ARGUMENT REQUESTED**

Christopher C. Costello
(ccostello@winston.com)
WINSTON & STRAWN LLP
200 Park Avenue
New York, NY 10166
Telephone: (212) 294-6700

George C. Lombardi (admitted *pro hac vice*)
(glombard@winston.com)
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
Telephone: (312) 558-5969

John Rosenthal (admitted *pro hac vice*)
(jrosenthal@winston.com)
WINSTON & STRAWN LLP
1700 K Street, N.W.
Washington, D.C. 20006
Telephone: (202) 282-5000

Joe G. Hollingsworth (admitted *pro hac vice*)
(jhollingsworth@hollingsworthllp.com)
Katharine R. Latimer (admitted *pro hac vice*)
(klatimer@hollingsworthllp.com)
Eric G. Lasker (admitted *pro hac vice*)
(elasker@hollingsworthllp.com)
HOLLINGSWORTH LLP
1350 I Street, N.W.
Washington, DC 20005
Telephone: (202) 898-5800
Facsimile: (202) 682-1639

Attorneys for Defendant
MONSANTO COMPANY

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## I. INTRODUCTION

The dispositive regulatory history and legal precedent that require dismissal of plaintiffs' Second Amended Complaint are undisputed. Plaintiffs' complaint rests upon two arguments: (1) that Monsanto should be held liable under state tort law for failing to adequately warn of a risk of cancer and other chronic health risks from exposure to glyphosate, and (2) that Monsanto should be held liable under New York General Business Law ("GBL") §§ 349 & 350 for the allegedly false statement on the Roundup® label that "glyphosate targets an enzyme found in plants but not in people or pets." Sec. Am. Compl. ¶ 17, ECF No. 17. Plaintiffs do not deny, however, that the United States Environmental Protection Agency ("EPA") has consistently concluded over the past 25 years that glyphosate does not pose a risk of cancer or chronic health effects and that EPA repeatedly has approved Roundup® labeling without warnings of such purported risks, thereby rejecting any finding that Roundup® is misbranded. *See* 7 U.S.C. § 136(q)(1)(A); 40 C.F.R. § 152.112(f) (1988). Nor do plaintiffs deny that EPA (as well as the New York Department of Environmental Conservation) has expressly approved the specific statement upon which their GBL claims are based, a fact that another federal district court very recently held requires dismissal of such claims. *See Mirzaie v. Monsanto Co.*, No. CV 15-04361DDP(FFMx), 2016 WL 146421 (C.D. Cal. Jan. 12, 2016), *appeal docketed*, No. 16-55228 (9th Cir. Feb. 12, 2016).

It is thus undisputed that plaintiffs seek to impose state law requirements that are different from EPA's specific regulatory requirements for Roundup®'s labeling under FIFRA. The United States Supreme Court and this Court each have held that such state law requirements are expressly preempted by 7 U.S.C. § 136v(b), which provides that a state "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from

those required under this subchapter." *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 452 (2005); *Fox v. Cheminova, Inc.*, 387 F. Supp. 2d 160, 167 (E.D.N.Y. 2005). Plaintiffs' contention that the Court can ignore EPA's specific regulatory requirements for Roundup® labeling in its preemption analysis and engage instead in an abstract comparison of federal and state labeling standards is directly contrary to this governing precedent. *See Bates*, 544 U.S. at 453 ("[s]tate-law requirements must . . . be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards"); *Fox*, 387 F. Supp. 2d at 168-69 (basing preemption analysis on review of EPA's specific regulatory decisions with respect to the labeling of the herbicide at issue).

Plaintiffs likewise have no answer to Monsanto's separate arguments for dismissal. Plaintiffs concede that the safe harbor provisions of GBL §§ 349 & 350 preclude consumer fraud and false advertising claims where the EPA has – as it has here – "explicitly endorsed the particular facet of the labeling which is claimed to be inadequate." Pl.'s Mem. P. & A. Opp'n Def. Monsanto Co.'s Mot. Dismiss Pls.'s Sec. Am. Compl. (Opp.) at 23 (quoting *Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144-45 (S.D.N.Y. 1987)). Plaintiffs also do not deny that the allegedly false statement in the Roundup® label is identical to statements independently made about glyphosate by federal and state regulators, and plaintiffs further do not cite a single case in which a court has ever allowed a Section 349 or 350 claim to proceed for recovery of personal injury damages. Finally, plaintiffs do not deny that they had the burden to plead an alternative feasible design for their non-warnings-based common law claims, and they make no effort to meet that burden.

Accordingly, and for the reasons set forth in Monsanto's opening brief, plaintiffs' Second Amended Complaint should be dismissed.

## II. ARGUMENT

### A. Plaintiffs Cannot Avoid Preemption By Disregarding EPA's Specific Regulatory Requirements For Roundup® Labeling.

Plaintiffs' opposition to preemption of both their warnings-based and their GBL claims is based upon a fundamental misstatement of governing law. Plaintiffs argue that this Court should "disregard[]" EPA's repeated approval of the language in the Roundup® labeling and consistent findings over the past 25 years that glyphosate does not cause cancer, *see* Opp. at 9 n.3, and instead engage solely in an abstract comparison of the general standards for liability under state and federal law. *See* Opp. at 8-10 (arguing that the elements of state common law and GBL §§ 349 & 350 mirror the general requirement under federal law that herbicide labeling contain warnings adequate to protect human health and the environment). But the Supreme Court in *Bates* made clear that a court's preemption analysis must be guided not only by a comparison of state and federal law standards but also by the "content" of EPA's specific regulatory determinations about the product at issue. *Bates*, 455 U.S. at 453.

The Supreme Court thus remanded the warnings-based claims in that case for further consideration, with specific instructions that the lower court compare plaintiffs' state law claims to EPA's regulatory decisions regarding the defendant's herbicide. *Id.* at 453-54. The Supreme Court explained that a plaintiff cannot avoid preemption based on "nominally equivalent labeling requirements." *Id.* at 454. Rather, a plaintiff must show that the state and federal requirements for the pesticide at issue are "genuinely equivalent," because "a manufacturer should not be held liable under a state labeling requirement subject to § 136v(b) unless the manufacturer is also liable for misbranding as defined by FIFRA." *Id.* These instructions – and the Court's decision to remand the warnings-based claims – would not have been necessary if the preemption

question could be decided based upon a sterile comparison of state and federal law without consideration of EPA's herbicide-specific labeling determinations.

This Court explained the proper approach to FIFRA preemption in *Fox v. Cheminova*, a case not mentioned in plaintiffs' opposition brief. As Monsanto noted in its opening brief, this Court explained in *Fox* that "*Bates* makes crystal clear that FIFRA 'preempts any statutory or common law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations.'" *Fox*, 387 F. Supp. 2d at 167 (quoting *Bates*, 544 U.S. at 452). In *Fox*, the parties had "not addressed or made a real factual issue of whether the State law labeling claims are 'genuinely equivalent' to FIFRA." *Id.* at 167. To resolve this factual issue, this Court examined the history of the EPA's specific regulatory decisions regarding the labeling of the pesticide at issue, noting: "[a]t bottom, the Court's inquiry is here whether the Fyfanon label was in defiance of FIFRA (and the EPA's) requirements. This determination turns on the timing of the amendment to the Fyfanon label." *Id.* at 168. The Court then engaged in a detailed analysis of EPA's labeling decisions for Fyfanon, including the fact that EPA had told the defendant to revise the Fyfanon label in January 1997 but that the product sold to the plaintiff in the fall of 1999 did not contain the EPA-required language. *Id.* at 168-70.

Plaintiffs do not cite to any contrary authority supporting their content-blind view of preemption. Plaintiffs' point to *Stengel v. Medtronic, Inc.* as "established precedent holding that parallel [state law] requirements are not in addition to or different from their federal counterparts." Opp. at 12. But *Stengel* – like *Fox* – makes clear that the determination whether state and federal requirements are parallel turns on the specific federal regulatory decisions regarding the labeling of the product at issue. *See Stengel v. Medtronic Inc.*, 704 F.3d 1224,

1227 (9th Cir. 2013) (discussing regulatory history in which FDA had sent a warning letter to the defendant stating that the product was misbranded under federal law). *DJ Coleman, Inc. v. Nufarm Americas., Inc.*, 693 F. Supp. 2d 1055 (D.N.D. 2010) is likewise unavailing, because the court there concluded that plaintiffs had not identified a state law requirement that could parallel federal requirements under any circumstances, obviating any need for any further, pesticide-specific review.

Plaintiffs also point to a twenty-year-old false advertising lawsuit filed against Monsanto by the New York Attorney General. That lawsuit did not address a purported risk of cancer or the alleged actionable statement in the Roundup® label here regarding the shikimate enzyme, and the Attorney General's allegations were never adjudicated.[1] As noted herein, New York State has expressly approved the Roundup® labeling and language at issue in this case. *See* Mem. Supp. Mot. Dismiss (Mot.) at 7. But in any event, as plaintiffs concede, the 1996 lawsuit was predicated on the Attorney General's assertions that Monsanto had made representations that "contradicted several statements *required on the EPA-approved label for Roundup*." Opp. at 18.

Plaintiffs do not – because they cannot – make any such assertions here. Plaintiffs have no response to Monsanto's showing, based upon judicially-noticeable government records,[2] that EPA specifically has approved the very statement in the Roundup® label upon which they

[1] Plaintiffs likewise seek to rely upon a notice of *proposed* rule-making in California under Prop 65. *See* Opp. at 13. As the responsible California official has explained, however, California has not made any final determination whether glyphosate will be listed under Prop 65 or that a listing, if made, would require any additional warnings. *See* Lauren Zeise, *Glyphosate has not been banned*, The Fresno Bee, http://www.fresnobee.com/opinion/letters-to-the-editor/article60100966.html. Nor has there been any adjudication whether such a listing, if made, would be lawful.

[2] *See Paskar v. City of New York*, 3 F. Supp. 3d 129, 134 (S.D.N.Y. 2014) (citing cases) ("Official government reports and other types of government records are appropriate for judicial notice.").

premise their GBL claims. Through those claims, plaintiffs are impermissibly asking the Court under state law *to enjoin Monsanto from using an EPA-approved label* required under federal law. *See* Mot. at 12-14. Nor do plaintiffs dispute the 25-year history of EPA determinations that glyphosate "does not pose a cancer risk to humans" and that "no harm will result to the general population and to infants and children from aggregate exposure to the combined residues of glyphosate . . . ." Mot. at 6, 11-12; *see also Mirzaie*, 2016 WL 146421, at *2 ("There can be no dispute that Plaintiffs seek to impose a labeling requirement different or in addition to that required under FIFRA, as the Roundup® label to which Plaintiffs object, and which Plaintiffs seek to alter, was approved by the Environmental Protection Agency in 2008."). Plaintiffs weakly argue that EPA's Group E classification of glyphosate in 1991 ("evidence of non-carcinogenicity"), "should not be interpreted as a definite conclusion that [glyphosate] will not be [carcinogenic] under any circumstances." Opp. at 9 n.3. But even if this Court could ignore EPA's subsequent unequivocal statements that glyphosate "has no carcinogenic potential," Mot. at 11, this purported wiggle-room in EPA's 1991 classification would not support plaintiffs' necessary showing that EPA has required Monsanto under FIFRA to affirmatively warn about a risk of cancer. EPA quite plainly has not.

B. The Federal Misbranding Requirements Likewise Compel Preemption Of Plaintiffs' Claims.

Plaintiffs' attempt to rely on federal misbranding regulations to avoid preemption is unavailing. Plaintiffs argue that EPA's approval of the Roundup® label does not constitute a defense against a subsequent finding of misbranding under federal law, but that argument rests upon the fact that a manufacturer has a continuing obligation to adhere to FIFRA's labeling requirements as new and relevant information surfaces. *See Bates*, 544 U.S. at 438. Plaintiffs do not deny that EPA's approval of a herbicide label precludes a finding of misbranding *at the time*

*of* the approval. Federal law makes clear that EPA will approve a pesticide application only if "[t]he Agency has determined that the product is not misbranded as that term is defined in FIFRA . . . and its labeling and packaging comply with the applicable requirements of the Act . . ." 40 C.F.R. § 152.112(f) (1988).[3] Moreover, "[a]s long as no cancellation proceedings are in effect[,] registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of [FIFRA]." 7 U.S.C. § 136a(f)(2).

Accordingly, to rebut this *prima facie* evidence and avoid preemption here, plaintiffs would need to show that EPA only approved the Roundup® label in the past and that subsequent information had surfaced that would cause EPA to impose a new labeling requirement to include a cancer warning. Plaintiffs cannot make these showings. As the public record documents establish: (1) EPA has continued to approve new labeling for dozens of different Roundup® products with no cancer warnings, including as recently as this past year[4] and (2) EPA has continued to reject any purported cancer link based upon its own ongoing review of the scientific evidence, well after each of the named plaintiff's alleged exposures to Roundup®.

Far from supporting plaintiffs' non-preemption argument, the FIFRA misbranding regulations establish why plaintiffs' claims must be preempted. Under the misbranding regulations, "[s]pecific statements pertaining to the hazards of the product and its uses must be approved by the Agency," 40 C.F.R. § 156.70(c) (1988), and pesticide products may be

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[3] As plaintiffs acknowledge, EPA will not approve a product label unless the label "bear[s] precautionary statements describing the particular hazard [shown to exist through data or other information], the route(s) of exposure and the precautions to be taken to avoid accident, injury or toxic effect or to mitigate the effect." Opp. at 10 (quoting 40 C.F.R. § 156.70); *see also* 40 C.F.R. § 156.60 (1988) ("Each product label is required to bear hazard and precautionary statements for humans and domestic animals (if applicable) as prescribed in this subpart.").

[4] *See, e.g.*, EPA, *Roundup Weed and Grass Killer Concentrate Plus*, Pesticide Product Label System, http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:8:364151237157::NO::P8_PUID:39270.

distributed or sold only with the "labeling currently approved by the Agency." *See* 40 C.F.R. § 152.130(a) (1988). Accordingly, the warnings that plaintiffs would require under state tort law not only are *not equivalent* to the requirements imposed on Monsanto under federal law, but they would require Monsanto *to violate* federal law by adding statements of alleged product hazards that EPA has directly rejected.

Plaintiffs' warnings-based common law claims and GBL claims are preempted by federal law, and they must be dismissed.

C. Plaintiffs Do Not Rebut Monsanto's Separate Showing That They Have Failed To State A Claim Under GBL §§ 349 & 350.

In its opening brief, Monsanto explained that plaintiffs' GBL claims also fail because they: (1) are barred by the safe harbor provision of those statutes for government-approved statements, (2) are based upon the implausible assertion that a statement in the Roundup® label identical to statements routinely made by federal and state regulators is materially false and deceptive, and (3) do not seek damages recoverable under the statute. Plaintiffs' responses to these arguments are without merit.

Plaintiffs only response with regard to the GBL safe harbor provisions is to note that the provisions do not immunize statements that are not specifically approved by federal or state regulators. *See* Opp. at 23. But plaintiffs do not deny that the statement that forms the basis of their GBL claims *was* specifically approved both by EPA and the New York Department of Environmental Conservation. *See* Mot. at 7, 14. This is exactly the circumstance under which the safe harbor provisions apply. *See Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145 (S.D.N.Y. 1987). Accordingly, plaintiffs' GBL claims are statutorily barred.

Plaintiffs respond to Monsanto's showing that a reasonable consumer is not likely to be misled by the statement that "glyphosate targets an enzyme found in plants but not in people or

pets" by attaching an "expert" declaration stating that the shikimate enzyme can be found in gut microbiota. *See* Opp. Exhibit B at 2. This declaration misses the point. For purposes of this motion, Monsanto is not disputing the factual question whether the shikimate enzyme is present in gut microbiota. The legal question before the Court, however, is whether the EPA-approved statement on the label regarding humans and pets is false. *See Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 85 N.Y.2d 20, 26 (N.Y. 1995) (question whether statement is false for purposes of GBL §§ 349 and 350 "may be determined as a matter of law"). As Monsanto explained in its opening brief – and as plaintiffs' pointedly do not deny – humans and animals do not produce the shikimate enzyme, and the mode of action by which Roundup® targets that enzyme in plants is irrelevant to humans and animals. The Roundup® label says nothing about gut microbiota, and the alleged false statement in the label is no different than statements about glyphosate routinely made by state and federal regulators. *See* Mot. at 4-5, 16-17. Plaintiffs' request that the Court allow a consumer fraud or false advertising claim to proceed based upon a hyper-technical interpretation of the word "in" would result in "a tidal wave of litigation against businesses that was not intended by the Legislature." *Id.* (omitting internal quotations and citations).

Finally, plaintiffs do not cite a single case in which a plaintiff has ever recovered damages for personal injuries under GBL §§ 349 and 350, do not point to any language in those statutes stating that a party can recover personal injury damages, and do not explain why the Legislature would create such a remedy in place of the well-established common law tort remedies available for such damages. *See* Mot. at 20 (citing *Rice v. Kawasaki Heavy Indus., Ltd.*, No. CV-07-4031, 2008 WL 4646184, at *6 (E.D.N.Y. Oct. 17, 2008); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 67 (S.D.N.Y. 2002)). Plaintiffs rely on *Small v. Lorillard Tobacco*

*Co., Inc.*, 94 N.Y.2d 43 (N.Y. 1999), but as they concede, the plaintiffs in that case did not seek recovery under the GBL for injury to their health, and the court did not hold that such damages would be recoverable. The issue in that case was whether defendants' deception about the addictive nature of cigarettes led to "economic injuries resulting from addiction-induced purchases" and "prevented plaintiffs from making free and informed choices as consumers." *Small v. Lorillard*, 679 N.Y.S.2d 593, 599 (N.Y. App. Div. 1998), *aff'd*, 94 N.Y.2d 43 (N.Y. 1999). Moreover, the plaintiffs in *Small* were not separately seeking recovery for personal injuries under state tort law as plaintiffs are here. Sections 349 and 350 are not intended to provide duplicative recoveries for injuries recoverable under other existing legal doctrines. *See Servedio v. State Farm Ins. Co.*, 889 F. Supp. 2d 450, 452 (E.D.N.Y. 2012) (explaining that "[t]he types of injury that section 349 was intended to remedy are limited" and noting by way of example that "plaintiff's alleged injury must be independent of the loss caused by … breach of contract") (internal quotation marks deleted), *aff'd*, 531 F. App'x 110 (2d Cir. 2013); *Fleisher v. Pheonix Life Ins. Co.*, 858 F. Supp. 2d 290, 305 (S.D.N.Y. 2012) (holding that plaintiffs had not adequately alleged injury under Section 349 where plaintiffs were separately seeking recovery for an alleged breach of implied covenant of good faith and fair dealing based on the same alleged conduct). Because plaintiffs do not allege that they suffered any other recoverable damage, their GBL claims fail for this reason as well.

D. Plaintiffs Provide No Response Whatsoever To Monsanto's Showing That They Failed To Plead A Feasible Alternative Design In Support Of Their Non-Warnings-Based Claims.

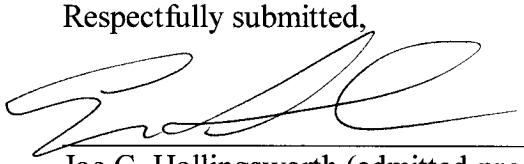
Plaintiffs do not dispute that they are required under New York law to plead a feasible alternative design before being allowed to proceed with non-warnings-based design defect claims. *See* Mot. at 20-21. Nor do they claim that they have satisfied this pleading requirement.

Plaintiffs accordingly concede that they have not satisfied their pleading burden for non-warnings-based claims, and those claims must be dismissed. Plaintiffs' straw man argument that their non-warnings-based claims are not preempted by FIFRA is irrelevant.

## III. CONCLUSION

For the foregoing reasons and the reasons set forth in its opening brief, Monsanto requests that this Court dismiss Plaintiffs' Second Amended Complaint with prejudice.

Respectfully submitted,



Joe G. Hollingsworth (admitted *pro hac vice*)
(jhollingsworth@hollingsworthllp.com)
Katharine R. Latimer (admitted *pro hac vice*)
(klatimer@hollingsworthllp.com)
Eric G. Lasker (admitted *pro hac vice*)
(elasker@hollingsworthllp.com)
HOLLINGSWORTH LLP
1350 I Street, N.W.
Washington, DC 20005
Telephone: (202) 898-5800
Facsimile: (202) 682-1639

Christopher C. Costello
(ccostello@winston.com)
WINSTON & STRAWN LLP
200 Park Avenue
New York, NY 10166
Telephone: (212) 294-6700

George C. Lombardi (admitted *pro hac vice*)
(glombard@winston.com)
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
Telephone: (312) 558-5969

John Rosenthal (admitted *pro hac vice*)
(jrosenthal@winston.com)
WINSTON & STRAWN LLP
1700 K Street, N.W.
Washington, D.C. 20006
Telephone: (202) 282-5000

Attorneys for Defendant
MONSANTO COMPANY